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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,658

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EXAMINER

DOE, SHANTA G

ART UNIT

PAPER NUMBER

1797

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,658	<b>Applicant(s)</b> MARLBOROUGH ET AL.	
	<b>Examiner</b> SHANTA G. DOE	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/27/2006</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 6, the claim limitation states "different capture analyses". The examiner is not sure what the applicant means by the above claim limitation. However, for examination purposes, the examiner believes the word "analyses" should be replaced by "analytes".

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
4. Claims 1-3, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sloane (WO 03/050537) in view of Cole et al (US 4246339) and Rossi (US 2003/0054344).

Regarding claim 1, Sloane discloses an apparatus for use in an assay process comprising: a pre- incubation chamber (14) defining a well (21), the well having a porous base (22); and a housing(12) carrying a porous membrane (16) disposed above and touching a body of absorbent material (18), and wherein a capture analyte is carried on the porous membrane and further including means for locating the pre- incubation chamber on top of the housing such that capture analyte is disposed under the base of the well of the pre- incubation chamber (see Sloane abs, fig 1,2,5c and 5d, page 5 lines 1 -13, page 16). Sloane fails to specifically disclose a chamber defining a

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plurality of wells and that a pattern of capture analyte is carried on the porous membrane located in the housing.

Cole et al (US 4246339) discloses an apparatus for use in an assay process comprising a chamber (10) defining a well or plurality of wells (20) wherein the well/wells have a porous base (22) (see abs, fig. 4, col. 1 lines 52 -60; col. 2 lines 52-56).

Rossi (US 2003/0054344) discloses that it is known in the art to form an array (pattern) of capture (immobilized) analyte on a porous membrane to be used in assaying. (See, [0031] [0034]).

In view of Cole and Rossi, it would have been obvious to one having ordinary skill in the art at the time of the invention to replace the chamber of the Sloane with the multiwell chamber of Cole and to replace the porous membrane with the capture analyte with the porous membrane as taught by Rossi having a pattern of capture analyte, since such a modification would enable the device to carry out high throughput assaying and also allow for simultaneously testing of different reagents on the capture analyte or same reagent on different analyte immobilized on the membrane.

Additionally, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the chamber of the Sloane comprise a multiwell chamber as taught by Cole and a porous membrane as taught by Rossi having a pattern of capture analyte, since all the claimed elements were known in the prior art and one skilled in the art would have combined the claimed elements with no change in their function and the combination would have yielded a predictable result of enabling

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the device to be used to carry out high throughput assaying and also to allow for simultaneous testing of different reagents on the capture analyte or same reagent on different analyte immobilized on the membrane.

Regarding claim 2, the combination as applied to claim 1 above discloses an apparatus as claimed in claim 1 wherein the housing is separate from the pre- incubation chamber (see Sloane fig 1).

Regarding claim 3, the combination as applied to claim 1 above discloses an apparatus as claimed in claim 1 wherein the housing is attached to the pre- incubation chamber in an arrangement in which the porous bases of the wells may be moved towards and away from the membrane (see Sloane fig 1 &2, page 5 lines 1 -13).

Regarding claim 5, the combination as applied to claim 1 above discloses an apparatus as claimed in claim 1 wherein the capture analyte is deposited in strips, in lines or in an array of dots (see Rossi fig 2) on the porous membrane by printing.

Regarding claim 6, the combination as applied to claim 5 above discloses an apparatus as claimed in claim 5. The combination fails to disclose the strip wherein each strip comprises several closely spaced lines of different capture analyses so that, in use, each well can be used to test for several reagents simultaneously.

However, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the strip comprise several closely spaced lines of different capture analyte in order to investigate different analyte on the same strip in parallel.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sloane (WO 03/050537) in view of Cole et al (US 4246339) and Rossi (US 2003/0054344) as applied to claim 2 above, and further in view of Fernwood et al (US 4,493,815) or Manns (US 5,047,215) .

Regarding claim 4, the combination as applied to claim 2 above discloses an apparatus as claimed in claim 2 wherein there is a separate housing (12) in which the membrane and body of absorbent material is located wherein the membrane is rectangular. The combination fails to specifically disclose that the housing defines a rectangular frame and that the membrane is substantially the same size and shape as the frame so that when inserted in the frame, the location of the frame defines the location of the membrane.

Fernwood et al (US 4,493,815) and Manns (US 5,047,215) disclose that it is well known in the art to have a device for assaying comprising a housing (Manns fig 1 (26) and Fernwood fig 1 (6)) wherein the housing defines a rectangular frame and the membrane (filter sheet Manns fig 1 (22) and Fernwood fig 1 (3))) disposed in the housing is also rectangular and is substantially the same size and shape as the frame.

In view of Fernwood and Manns, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the housing of the combined reference define a rectangular frame and to have the membrane disposed in the housing be substantially the same size and shape as the frame as taught by both Fernwood et al (US 4,493,815) and Manns (US 5,047,215) since it was well known in the art at the time of the invention to have assaying devices be of such construction.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sloane (WO 03/050537) in view of Cole et al (US 4246339) and Rossi (US 2003/0054344) as applied to claim 1 above, and further in view of Kopaciewicz et al (US 2004/0124142).

Regarding claim 7, the combination as applied to claim 1 above discloses an apparatus as claimed in claim 1 where the chamber comprises a plurality of wells having a porous base which depends below the underside of the pre- incubation chamber. However, the combination fails to specifically disclose that the porous base comprises a frit or porous plug.

Kopaciewicz et al (US 2004/0124142) discloses that it is known in the art to use porous plugs in wells where the porous plug serves to retain particles in a well (see Kopaciewicz [0006]).

In view of Kopaciewicz, it would have been obvious to one having ordinary skill in the art at the time of the invention to replace the porous base of the wells in the



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combination as applied to claim 1 with the porous plug as taught Kopaciewicz, since the substitution of one known porous base for another would have yielded a predictable result of allowing fluid to pass through the base while retaining particles (if any) within the well.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sloane (WO 03/050537) in view of Cole et al (US 4246339) and Rossi (US 2003/0054344) as applied to claim 2 above, and further in view of Fernwood et al (US 4,493,815) .

Regarding claim 8, the combination as applied to claim 2 above discloses an apparatus as claimed in claim 2 wherein there is a means of locating a pre-incubation chamber on top of the housing. However, the combination fails to specifically disclose that such means comprises pins depending from the underside of comers of the pre-incubation chamber and holes defined in comers of the housing.

Fernwood disclose an apparatus comprising a chamber (2) comprising a plurality of wells, a housing (6,) and a locating means wherein the locating means comprises pins depending from the underside of corners of the chamber and holes defined in corners of the housing (see fig 1col 5 lines 5 -15 ).

In view of Fernwood, it would have been obvious to one having ordinary skill in the art at the time of the invention to replace the means of locating the chamber on top of the housing in the combination as applied to claim 2 with the locating means comprising pins depending from the underside of comers of the chamber and holes

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defined in corners of the housing as taught by Fernwood, since the substitution of one known locating means/securing means for another would have yielded a predictable result of securing two separate pieces of a device together.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANTA G. DOE whose telephone number is (571)270-3152. The examiner can normally be reached on Mon-Fri 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GSD

/Walter D. Griffin/  
Supervisory Patent Examiner, Art Unit 1797